DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 26, 2014

Life Spine, Inc.
Mr. Randy Lewis
General Manager
2401 West Hassell Road, Suite 1535
Hoffman Estates, Illinois 60169

Re: K141905
Trade/Device Name: Pro-Link Wedge System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 04, 2014
Received: August 05, 2014

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141905

Device Name
The Pro-Link Wedge System

Indications for Use *(Describe)*
The PRO-LINK Wedge and screws are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

- Opening wedge osteotomies of Hallux Valgus
- Evans lengthening osteotomies
- Metatarsal/cuneiform arthrodesis

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Pro-Link Wedge System

Submitted By:
Life Spine
2401 W. Hassell Road, Suite 1535
Hoffman Estates, IL 60169
Telephone: 847-884-6117
Fax: 847-884-6118

510(k) Contact:
Randy Lewis
General Manager
Life Spine
2401 W. Hassell Road, Suite 1535
Hoffman Estates, IL 60169
Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: July 11th, 2014

Trade Name: Pro-Link Wedge System

Classification: HWC, CFR 888.3040, Class II
HRS, CFR 888.3030, Class II

Predicate Device: BioFoam Wedge System (K093950)
OrthoHelix Maxlock Extreme System (K113048)

Device Description:

The PRO-LINK Wedge System is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot. The implant is available in a range of sizes and footprints to suit the individual anatomical conditions of the patient. It is fabricated and manufactured from Polyetheretherketone (PEEK-OPTIMA LT1) with tantalum markers and titanium pins (Ti 6Al-4V ELI). The implant is hollow to permit packing with autogenous bone graft to help fusion. The implant has two pockets to permit placement of titanium bone screws (Ti 6Al-4V ELI) through the wedge to provide internal fixation. The implant also has one central threaded hole to permit the insertion of a titanium lock plate (Ti 6Al-4V ELI) to prevent screw back out.

All implants are intended for single use only and should not be reused under any circumstances. **Do not use any of the PRO-LINK Wedge System components with components from any other system or manufacturer. The PRO-LINK Wedge System components should never be reused under any circumstances.**

Intended Use of the Device:

The PRO-LINK Wedge and screws are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

- Opening wedge osteotomies of Hallux Valgus
- Evans lengthening osteotomies
- Metatarsal/cuneiform arthrodesis

Technological Characteristics:

The Pro-Link Wedge System is substantially equivalent to the predicate systems in terms of design, materials, and indications for use.

Material:

The PRO-LINK Wedge System is manufactured from implantable grade PEEK-Optima per ASTM F2026, incorporates tantalum markers per ASTM F560, and implantable grade titanium (Ti 6Al-4V ELI) per ASTM F136.

Performance Data:

Static and Dynamic Compression and Torsion testing in accordance with ASTM F2077, in addition to Finite Element Analysis, was presented to demonstrate the substantial equivalency of the Pro-Link Wedge System.

Conclusion:

The Pro-Link Wedge System was shown to be substantially equivalent to the previously cleared devices in indications for use, design, function, and materials used.